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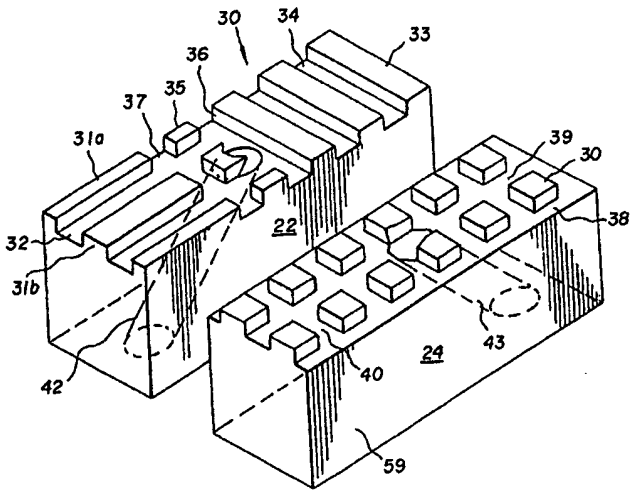

(57) Abstract

This invention is a composite allograft bone device (20) comprising a first bone member (22) body defining with a face that includes a plurality of intersecting grooves cut into the face of the body to define a plurality of spaced projections forming a pattern, and a second bone member (24) body defining a face that includes a plurality of angularly intersecting grooves cut into the face to form a plurality of spaced projections forming a second pattern. The projections on the second face fit into grooves (32) cut in the first face allowing the two bodies to be mated together with the spaced projections of each face fitting into the grooves (38) of the opposing face. The mated bodies form a composite bone device (20) which is provided with a through going bore (42) positioned at an angle to the longitudinal axis of the composite device (20), and a dowel (46) mounted in the through going bore (42) extending into the bone member bodies precluding the same from relative longitudinal movement.

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COMPOUND BONE STRUCTURE FABRICATED FROM ALLOGRAFT TISSUE

BACKGROUND OF THE INVENTION

1. Field of Invention

The present invention generally relates to allograft bone devices for surgical implantation into bone tissue and particularly to a composite allograft bone device constructed from two or more separate bone pieces made from allograft, autograft and xenograft bone tissue that can be constructed to have dimensions that are larger than the dimensions of naturally occurring bone suitable for implantation in a surgical site .

2. Description of the Prior Art

Allograft bone tissue is widely used in orthopedic, neuro-, maxillofacial, podiatric and dental surgery. Allograft tissue is valuable in these fields of surgery because it is strong and it biointegrates well over time with the recipient patient's tissue. Allograft bone tissue can be shaped for specific surgical applications by the surgeon or by a bone product manufacturer in a manufacturing environment before the allograft bone tissue is transferred to the surgeon. Unfortunately because of the size limitation of the bone material only devices of a certain size could be constructed.

Surgical implants constructed entirely from allograft bone tissue are generally superior to implants constructed from synthetic or nonabsorbable polymers or metals because allograft bone tissue is bioinert and integrates well with the surrounding tissues.

Allograft bone occurs in two basic forms: 1) cancellous bone (also referred to as trabecular bone) and 2) cortical bone. Cortical bone is highly dense and has a compound structure comprised of calcium hydroxyapatite reinforced with collagen fiber. This cortical bone material is the predominant load bearing component of long bones in the human body. Many shapes and forms can be fabricated from allograft cortical bone tissue including pins, screws, plates, intervertebral discs and the like for use in human surgery. Cortical bone has one serious limitation that plastics and metal do not have. Bone parts and bone products made from allograft cortical tissue are limited in size, dimension and shape because of the anatomical limits on the thickness and length of the source bone.

As an example, the largest long bone, the femur bone, has a thick cortical wall that varies in thickness from about two millimeters to about ten millimeters. The majority of the femoral cortical bone wall typically ranges from about three millimeter to

about eight millimeters in thickness. The length of the cortical tissue is also naturally limited by the size and the weight of the allograft tissue donor. Accordingly, specific implants fabricated from cortical bone have previously not been larger than these natural anatomical dimensions. The other long bones of the human body, the humerous, the tibia, the fibula, the radius, the ulna, the ribs, etc., are similarly limited in dimension. Shaped implants made from these other long bones are also necessarily limited in dimension.

The dimensional limit that has been achieved with single piece cortical bone is about 10mm x about 13mm cross-sections. The length of these sections can be much longer as they are taken from the long axis of the bone. The research that has been completed shows femoral sections ranging from 3mm x 4mm to 10mm x 10mm at the mid-shaft and tibial sections 3mm x 6mm to 10mm x 13mm at the proximal end.

Many medical problems and surgical procedures require implants larger than have previously been made out of allograft cortical tissue. It is desirable to have a surgical implant made entirely out of allograft cortical tissue that is larger than can be made from a single piece of naturally occurring bone. Two requirements must be met by any implant fabricated entirely from cortical bone, however, to achieve a successful surgical result. First, the components must be held together in such a way that the mechanical structure of the implant is not compromised during the surgical implantation procedure. Many surgical implants are implanted in the recipient patient with a large applied force. Many implants are actually hammered in as is the case for an intervertebral implant. Second, the compound structure of the implant must hold together during the post-operative period during which the allograft tissue is resorbed and remodeled.

The prior art contains many references directed to fasteners, spinal cages and devices which are constructed of inert metals or plastics which are used in bone repair. There are relatively few devices used in bone repair constructed of allograft bone because of the difficulty in obtaining and shaping the material and the natural limits placed on the size of the device based on the constraints of the sizes of the natural bone which can be shaped to form devices of a larger required size.

One example of an allograft device is disclosed in U.S. Patent Number 4,877,020 which shows a dowel made of bone having a helicoidal thread.

Another device is shown in U.S. Patent Number 4,932,973 where the use of a perforated bone matrix for use in insertion or implantation in a bone mass to promote

bone growth is disclosed.

Similarly U.S. Patent Number 5,112,354 discloses the preparation of an allograft bone segment for use in skeletal reconstruction. The bone segment is demineralized and a multiplicity of bores (described as pores) are drilled into the bone mass in a pattern to maximize the surface area of the implant. Some of the bores are drilled through the bone mass at the center of the hexagon pattern.

U.S. Patent Number 5,439,684 is directed toward various swollen demineralized bone constructions such as sleeves, rectangular pledgets and wedges. The pledgets and wedges can be used as invertebrate support blocks. The bone can be machined into a desired shape for implantation such as sheet, disc, ring, cube, cylinder or sliced and wrapped into a tubular shape. However, all of these bone structures are limited to the size and shape of the original material.

Another patent of interest is U.S. Patent Number 4,858,603 which shows a bone pin which is placed through an angular bore cut through two separate pieces of bone to hold the pieces together in a fixed secured relationship. The bone pin is made from a polymer which is absorbable in an animal body.

Until now, the only way that separate bone pieces could be joined together to arrive at a larger device has been to tongue and groove the respective pieces which creates shearing areas and limits the use to which such constructed device could be used. This is a significant problem where a device is placed under stress and shearing forces as for example where it is hammered into place between vertebrae or into other bone areas. The first disclosure of joining together separate pieces of allograft bone is believed to be set forth in various articles by F. Albee. This disclosure also show the machining of dowels, pins and screws from bone. F. Albee, Bone Graft Surgery in Disease, Injury and Deformity p. 22 (1940); and F. Albee, The Improved Albee Bone Mill, American Journal of Surgery p. 657 (March 1938).

Accordingly, there is a need for implantable shaped structures made entirely out of cortical bone tissue that are larger than naturally occurring bone structures and are made wholly out of cortical tissue without using external, non-cortical fasteners or adhesives.

SUMMARY OF THE INVENTION

The present invention is directed toward a shaped structure made out of allograft cortical bone tissue that is larger than the natural dimensions of a cortical bone layer made by combining two or more smaller pieces to form a compound bone structure.

The compound bone structure is comprised of a first bone member having a first mating face constructed and arranged to support a load applied in a direction that is normal to the first mating face and to receive and engage a complimentary mating face of a second bone member. The second bone member has a mating face that is complimentary to the first mating face of the first bone member. The second mating face is constructed and arranged to support a load applied in the direction normal to the second mating face and to engage the first mating face so that the first and second bone members cooperate to form the compound bone structure.

The compound bone structure has an exterior surface that can be shaped to form an implant that can support the anatomical load and orient the implant in the surgical site so that the anatomical load is applied to the engaged first and second mating faces in the normal direction. Complimentary mating structures formed on the first and second mating faces prevent displacement of the first bone member with respect to the second bone member in both a longitudinal direction and a transverse direction when an anatomical load is applied.

At least one pin is placed through the component bone members of compound bone structure at an oblique angle to the plane of the mating faces and extends through the full thickness of the compound bone structure.

It is an object of the invention to make a compound bone structure from bone tissue of smaller bone segments for use in implantation into a surgical site and to support an anatomical load applied to the compound bone structure during a post-operative period while the implanted bone tissue is resorbed and remodeled.

It is another object of the invention to fabricate shapes out of allograft cortical tissue that would enable larger parts to be made out of cortical tissue without using external non-cortical fasteners or adhesives.

It is yet another object of the invention to form a compound bone structure which is implantable and is larger than bone pieces that are found in nature.

These and other objects, advantages, and novel features of the present invention will become apparent when considered with the teachings contained in the

detailed disclosure along with the accompanying drawings.

BRIEF DESCRIPTION OF THE DRAWINGS

FIG. 1 shows an exploded flipped perspective elevational view of the inventive compound bone device;

FIG. 2 shows a top plan view of one of the bone members of the inventive compound bone device shown in Figure 1;

FIG. 3 shows an end elevational view of the bone member shown in Figure 2;

FIG. 4 shows a top plan view of a second member of the inventive compound bone device shown in Figure 1;

FIG. 5 shows an end elevational view of the bone member shown in Figure 4;

FIG. 6 shows an assembled perspective elevational view of the inventive compound bone device with the respective mating faces in phantom and an inserted dowel;

FIG. 7 shows an exploded flipped perspective view of the inventive compound bone device with dowel removed and the dowel bore in phantom;

FIG. 8 shows an exploded side elevational view of another embodiment of the compound bone device;

FIG. 9 is an assembled side elevational view of the compound bone device of FIG. 8 showing the dowels removed and dowel bores in phantom;

FIG. 10 is an plan view of the first bone member taken along line 10'-10' in FIG. 8;

FIG. 11 is a plan view of the second bone member taken along line 11'-11' in FIG. 8;

FIG. 12 is a side elevational view of the compound bone device shaped to form an implant for insertion between vertebra for spinal fusion with the bores shown in phantom;

FIG. 13 is a cross-sectional view of the compound bone device of FIG.12 taken along the center axis of the device;

FIG. 14 is a schematic view of the compound bone device shown in Figures 12 and13 in a surgical site formed between an upper and a lower vertebrae in lumbar

portion of a spine; and

FIG. 15 is an exploded perspective view of an alternative embodiment of a smooth outer surfaced compound bone device.

DETAILED DESCRIPTION OF THE PREFERRED EMBODIMENT

The preferred embodiment and the best mode of the invention is shown in FIGS. 1-7. Figure 1 shows an exploded side view of a compound bone device 20 with a first bone member 22 and a second bone member 24 flipped for viewing. The first and second bone members 22, 24 are constructed from rectangular blocks of bone tissue that have been machined or shaped by other suitable means. Each bone member 22, 24 has a mating face or engagement surface 26 and 28 as shown in Figures 2 and 4 respectively that has been shaped to form integral mating projections or teeth 30 on each face 26, 28 so that the members 22, 24 can be engaged to form the compound bone device 20 shown in FIG. 6.

Bone member 22 has a mating face 26 constructed with three bar projections 31 separated by grooves 32 formed on one end. The bar projections 31 run parallel to the longitudinal axis of the bar member and extend along the mating face less than ½ the length of the bar member. The grooves 32 are preferably around 2 to 2.12mm in width and the side bars 31(a) have a width which is less than the width of the center bar 31(b). The other end of the bone member 22 has three bar projections 33 separated by grooves 34 running transverse the longitudinal axis and extending across the width of the bone member 22. The midsection of the bone member has a plurality of rectangular projections 35 formed by extending grooves 32 up to the side wall 36 of the inner transverse bar 33. The rectangular projections 35 are separated from the axially aligned bar members 31 by a groove 37 and the side wall 36 of inner transverse bar 33 by groove 37(a). The bars 31(b), 33 and center rectangular projection 35(a) have a width of approximately 2mm.

Bone member 24 is formed with grooves 38 along each longitudinal side of the body and is also provided with a central groove 39 extending longitudinally the length of the bone member 24. Grooves 40 run across the width and transversely intersect grooves 38 and 39 forming projections 30. The grooves 38 located on opposite sides of the bone member 24 receive the side bars 31(a) and the side rectangular projections 35.

The mating projections or teeth range from .5 to 2.0mm in height,

preferably 1.0mm and are formed by cutting a plurality of slots, grooves or channels ranging from 1 to 4mm in width with a generally rectangularly shaped cross sections in each mating surface 26, 28 of the bone members. The channels or grooves 38-40 are of equal width dimensions and preferably have a width ranging from 2.0mm to 2.12mm apart.

The mating projections 30 and the channels on the bone members 22, 24 form complimentary inverse patterns that allow the members 22, 24 to be engaged or meshed together by press fitting the patterns together. This engagement and relationship of the various projections prevents relative motion between the members 22, 24 in both the transverse and longitudinal directions to stabilize the compound bone device 20 during subsequent machining of the exterior surface of the device 20 and during or after implantation in a surgical site.

Two biased or angled bores 42 and 43, respectively, extend through each bone members 22, 24. The bores 42 and 43 are shown in phantom in FIGS. 6 and 7. The bores 42 and 43 are oriented so that when the members 22, 24 are engaged, the bores 42 and 43 are axially aligned to form a continuous first bore 47 through the compound bone device 20. A cylindrical pin 46 shown in FIG. 6 preferably made of cortical bone tissue is press fit into the continuous bore 47 to prevent the separation of the members 22, 24.

Thus, the mating surfaces 26, 28 of the bone members 22, 24 are secured together by at least one pin positioned at an oblique angle to the plane of the engaged mating surfaces and extending the full thickness of the compound bone device 20. In the preferred embodiment shown in FIGS. 1-7, the wall surrounding bore 47 is cylindrical and pin 46 is cylindrical. The pin has a diameter slightly greater than the diameter of the bore 47 so that the pin is retained in the bore by an interference fit and is constructed with a tolerance of 0.03mm to 0.25mm with respect to the bore diameter. If desired a suitable medical adhesive can be use to insure that the pin stays in the bore during insertion.

It will be appreciated that three or more bone members can be fastened together by forming projections on both sides of the bone members. As an example, bone member 24 could be provided with an identical mating face on its opposite side which would engage another bone member shaped identical to bone member 22.

Figure 8 shows an alternative embodiment of the compound bone device 120 constructed with a first bone member 122 and a second bone member 124. The first

and second bone members 122, 124 are constructed from rectangular blocks of bone tissue that has been machined or shaped by other suitable means. Each bone member 122, 124 has a mating face or surface 126 and 128 as shown in Figures 10 and 11 respectively that has been shaped to form integral mating projections or teeth 130 on each face 126, 128 so that the members 122, 124 can be engaged to form the compound bone device 120 shown in FIG. 9.

Each bone member 122, 124 has been shaped to form a groove 131 on each longitudinally extending side of each member so that when the members are engaged as shown in FIGS. 9 and 12, a composite groove 133 extends longitudinally the length of the compound bone device 120. The groove 133 is located on opposite sides of the compound bone device 120 and serves as a holding slot for the instrument which holds the compound bone device 120 while it is being machined. One end of each bone member 122, 124 has been machined to provide a slightly extended end surface 134. The raised end surfaces 134 cooperate when the members 122, 124 are engaged to form an impact surface 135 that can be struck with a hammer or other suitable instrument during a surgical procedure to implant the compound bone device 120 into a surgical site.

The mating projections or teeth 130 range from .5 to 2.0mm in height, preferably 1.0mm and are formed by cutting a plurality of slots, grooves or channels 132 ranging from 1 to 4mm in width with a generally rectangular shaped cross section in each mating surface 126, 128 of the bone tissue. The channels 132 are of equal dimensions and are preferably equally spaced about 2.0mm to 2.12mm apart. The channels 132 are preferably angled at +45 degrees and –45 degrees with respect to the longitudinally extending grooves 131.

The mating projections or teeth 130 formed by the channels 132 are comprised of a plurality of identical longitudinally spaced rectangular projections in a central portion of each mating surface 126, 128. A larger triangular shaped projection 136 extends transversely between the longitudinal edges at one end of each of the mating surface 126, 128. The triangular shaped projection 136 has the same height as the projections 130.

The mating projections 130 and the channels 132 on the bone members 122, 124 form complimentary inverse patterns that allow the members 122, 124 to be engaged or meshed together by press fitting the patterns together. This engagement prevents

relative motion between the members 122, 124 in both the transverse and longitudinal directions to stabilize the compound bone device 120 during subsequent machining of the exterior surface of the device 120 and during or after implantation in a surgical site.

As shown in FIGS.10 and 11, the channels 132 are machined in the cortical bone to preferably a 1mm depth and are angled at +45 degrees and –45 degrees in relation to edge 131 of each member 122, 124. The plus and minus 45 degree angles are the preferred angles for forming complimentary patterns on each surface 122, 124 because of ease of manufacturing, but any angle within a range of from about 15 degrees to about 75 degrees could be used in a similar way to cut other patterns forming mating surfaces 126, 128. It is understood that a degree of tolerance is necessary in the manufacturing process to assure that the members 122, 124 can be engaged and still provide sufficient structural support to the compound bone device 20. In all of the described embodiments, the maximum tolerance between the engaged parts at the surface ranges from .025mm to .1mm.

Two biased or angled bores 142, 144 and 143, 145, respectively, extend through each bone member 122, 124. The bores 142, 144, 143, 145 are shown in phantom in FIGS. 8 and 9. The bores 142, 144, 143, 145 are arranged so that when the members 122, 124 are engaged, the bores 142, 144, 143, 145 are axially aligned to form a continuous first bore 147 and a continuous second bore 149 through the compound bone device 120. Two cylindrical pins 146 shown in exploded view in FIG. 8 preferably made of cortical bone tissue are press fit into each the continuous bores 147, 149 to prevent the separation of the members 122, 124.

Thus, the mating surfaces 126, 128 of the bone members 122, 124 are secured together by at least one pin positioned at an oblique angle to the plane of the engaged mating surfaces and extending the full or partial thickness of the compound bone device 120. The wall surrounding each bore 147, 149 is cylindrical and each pin 146 is cylindrical. The pin has a diameter slightly greater than the diameter of the bores 147, 149 so that the pins are retained in the bores by an interference fit and is constructed with a tolerance of 0.03mm to 0.25mm with respect to the bore diameter. If desired a suitable medical adhesive can be use to insure that the pins stay in the bores during insertion. It can be appreciated that the bores and pins can have other configurations as, for example, rectangular, triangular and the like. When the bone members 122, 124 are engaged and

the pins 146 are inserted to hold them together, an exterior surface 148 of the compound bone device 120 can be shaped to form a suitable im
surgical site. If desired, the exterior surface 48, 148, 248, 348 can be scored 59, 259 or otherwise configured to present gripping means which grips surrounding tissue when the compound bone device is implanted into the surgical site. The pins 146 provide sufficient structural reinforcement for the compound bone device to allow the device 120 to be machined to form the desired shape. Another compound bone device 220 is shaped so that when the device 220 is implanted in a surgical site, the anatomical load of the patient is applied in a direction that is normal to the engaged mating faces 226, 228. The normal direction is shown in FIG. 15 by an arrow N. It can be appreciated from the cross-section that when the two members 222, 224 are engaged, the projections on the first member 222 are disposed between or adjacent channels on the second member 224 to prevent the relative movement between the members 222, 224 in the longitudinal and transverse directions. There are some empty spaces between the mating faces 226, 228 of the compound bone device 220.

FIGS. 12, 13 and 14 show that the exterior surface 248 of the compound bone device 220 can be shaped to form a intervertebral implant for the lumbar spine for insertion between vertebrae to fuse the vertebrae. The compound bone device 220 can be machined to provide a sloped and rounded proximal end 250 and distal end 252 for easy intervertebral insertion.

FIG. 13 shows a cross-section of a compound bone device 220 taken through FIG. 12. The cross-section shows that the bores 247, 249 are angled with respect to the normal direction N. It can be appreciated that the normal direction is generally perpendicular to each of the engaged surfaces of the compound bone device 220. Each mating face 226, 228 is constructed and arranged to support a load that is applied in a direction that is normal to the surface. When the surfaces are engaged they can support an applied normal load and, because they are engaged, the normal load will not displace the bone members 222, 224 in the longitudinal or transverse directions relative to one another.

The bores 247, 249 generally form oblique angles with the engaged surfaces. It can be appreciated from FIGS. 12 and 13 that the oblique angles of the bores 247, 249 are complimentary. That is, the angle of bore 247 is the inverse of or the negative of the angle of bore 249. The preferred angle of bore 247 with a line generally extending

between the two faces is about 110 degrees and therefore the angle of bore 249 is negative 110 degrees.

FIG. 14 shows a schematic representation of the compound bone device 220 implanted in a surgical site 62 in the lumbar spine between an upper vertebra 64 and a lower vertebra 66 to fuse the vertebra. In this surgical procedure, an intervertebral space is enlarged and shaped to receive the allograft compound bone device 220 implant. The compound bone device 220 is inserted in the surgical site 62 so that the applied anatomical load N is applied in a direction that is normal or perpendicular to the engaged mating faces 226, 228.

The exterior surface 248 of the compound bone device 220 is shaped to support the applied load in a direction that is normal to the engaged faces 226, 228 and to maintain the orientation of the implanted compound bone device 220 in the surgical site 62 throughout the post-operative period.

The engaged faces 26, 28, 126, 128, 226, 228 and 326, 328 support the major anatomical load of the patient during the post operative recovery period. The engagement between the respective projections 30, 130, 230 and 330 on the two mating faces 26, 28, 126, 128, 226, 228 and 326, 328 assure that the first and second bone members 22, 24, 122, 124, 222, 224 and 322, 324 do not move relative to one another in the longitudinal or transverse directions during the post operative period.

It is desired that the compound bone devices 20, 120, 220 and 320 hold together during the post operative period to allow resorption and remodeling to occur in the allograft tissue and pins are used to hold the same together. The pins 46, 146 (pins 246 not shown), 346 inserted in bores 47; 147, 149, 247, 249 and 347 can be made of cortical, allograft tissue. The outer surface of each cortical pin is entirely within and surrounded by the bone mass of the compound bone device so that the pin is substantially protected from the biochemical attack that occurs from normal biological and biochemical processes as the implant is integrated into the bone of the patient. Only the end surfaces 446 and 546 of the pin 46, 146 are exposed, but this results in minimal structural degradation of each pin.

The biological and biochemical process cause a slow absorption of the implanted bone to occur over time. This absorption could structurally degrade the interlocking bone members of the compound bone device. Because the anatomical load is normal to the mating complimentary surfaces, the anatomical load can be sustained even

during tissue degradation. Because the pins are substantially protected from the biochemical mechanism of absorption, the pins will continue to secure the bone members together long enough to allow full healing and integration to occur. The cortical pins 46, 146 and 346 are embedded and held tightly in the mass of the implant and are protected from the biochemical attack of the patient except at the two end surfaces 446 and 546 of each pin. The pins 46, 146, and 346 remain structurally intact during the post-operative period to help maintain the structural stability of the compound bone device 20, 120, 220 and 320.

The normal absorption mechanisms that occur during the healing process also tend to structurally degrade the two engaged bone members of the compound bone device 20, 120, 220 and 320 during the post operative period. Because the anatomical load is normal to the engaged surfaces, the applied load can be supported by the device 20, 120, 220 and 320 even though some degradation of the allograft tissue does occur. Because the length of the interlocking pins 46, 146 and 346 are protected from biochemical degradation, the pins continues to secure and hold the two bone members 22, 24; 122, 124; 222, 224 and 322, 324 in place long enough for full resorption and remodeling to occur. The cortical tissue of the compound bone device 20, 120, 220, and 320 has been observed to last 6 to 12 months before being fully integrated into the host patient.

The assembled compound bone device 220 shown in the schematic view in FIG. 14 was tested in a cadaver lab in which it was inserted into the lumbar spine. The procedure requires that the assembly be hammered using considerable force into the intervertebral disc space. Four compound bone devices were successfully inserted into the spine with no signs of impact damage due to the insertion.

Another embodiment of the compound bone device 320 is shown in FIG. 15 which shows a first bone member 322 and a second bone member 324 in exploded view with a pin 346. The mating faces 326, 328 and projecting teeth 330 can be engaged and secured together with pin 346 to form the compound bone device 320. The exterior 348 has been shaped to form a rectangular shape with rounded corners.

It can be understood by one skilled in the art that the preferred embodiment described above is intended as an example only to teach the broad principles of the invention and is not intended to be limiting. It can be understood, for example, that the mating projections or teeth 30, 130, 230, 330 are constructed and arranged so that when the

two mating faces 26, 28 and 126, 128 and 226, 228 and 326, 328 are engaged, there is no significant relative movement between the bone members in the longitudinal and transverse directions outside of that permitted by the manufacturing tolerances and by any structural changes that occur in the bone device during the post operative period.

It is appreciated that many geometric configurations of projections on each mating face can provide suitable structures to prevent relative movement between the bone members in the longitudinal and transverse directions.

In general, a plurality of mating projections and channels forming mating spaces are provided on a first mating face and a plurality of mating projections and mating spaces are provided on a second mating face. When the faces are engaged or mated, the mating teeth on the first face are disposed within the mating spaces on the second mating face and the mating teeth on the second mating face are disposed within the mating spaces on the first mating face to prevent the relative movement between the bone members in the longitudinal and transverse directions when the bone members are inserted into a surgical site or are disposed in a surgical site during a post operative period.

In general, each mating face is constructed and arranged to support an applied load applied in a normal direction and to engage a mating face with complimentary projection receiving construction.

The two piece design for the compound bone devices described above allow for constructions 10mm x 25mm or larger. This assembly technique considerably broadens the use of allograft tissues by allowing much larger implants to be formed than could have been attained from the normal human anatomy.

It can also be understood that because the preferred embodiment is illustrative only, as it is contemplated to provide a compound bone device comprised of more than two bone members. In such a case, the compound bone device can be thought of as being comprised of an upper member, a middle member(s) and a lower member. The upper and lower members are provided with a single mating face and the middle member(s) is provided with two mating faces generally disposed on opposite sides thereof so that the three or more bone members or pieces can be engaged and pinned together with at least one embedded cortical bone pin, preferably located at an oblique angle to the longitudinal plane of the mating surfaces.

Because bones are irregularly shaped and because not all applications of the

invention require that the implant support an anatomical load that is applied in generally one direction, it can be understood that if more than one pair of engaged mating faces is present in a single compound bone device, the pairs need not necessarily be parallel nor do the individual members of each pair have to be generally planar to form a compound bone device.

The compound bone device can be constructed and arranged to support a load applied in a direction that is generally normal to the two pairs of engaged faces so that the bone device can support an anatomical load and prevent the relative displacement of the three bone pieces in a longitudinal or transverse direction.

It can further be understood that because the illustrated embodiment is exemplary only, it is contemplated to provide compound bone devices which are shaped for many applications and that the compound bone device design is not restricted to use in the lumbar spine for spinal fusion. A compound bone device comprised of two or more bone members can be shaped during the manufacturing process to form compound bone pins, bone screws, plates, discs, wedges , blocks and other devices of various configurations.

The compound bone device can be fabricated from xenograft, autograft or allograft bone tissue, and it is contemplated to use any suitable bone tissue from any source to form a compound bone device.

It is also understood that although it is preferred to fabricate the compound bone device using only cortical bone without the use of adhesives or synthetic absorbable or nonabsorbable polymers or metals, it is within the scope of the invention to additionally secure together the bone members with any suitable surgical bone adhesive or with a synthetic absorbable or nonabsorbable polymer or in any combination with or without at least one pin made of bone tissue.

In the foregoing description, the invention has been described with reference to a particular preferred embodiment, although it is to be understood that specific details as shown are merely illustrative, and the invention may be carried out in other ways without departing from the true spirit and scope of the following claims.

WHAT I CLAIM IS:

Claim 1. A compound bone device made from sterile bone tissue for implantation into a surgical site which supports an anatomical load applied to the compound bone device during a post-operative period while the implanted bone tissue is being resorbed and remodeled, comprising:

a first bone member defining a first mating face constructed and arranged to support a load in a direction that is normal to the first mating face and to receive and engage a complimentary mating face of a second bone member;

a second bone member defining a second mating face that is complimentary to the first mating face of the first bone member constructed and arranged to support a load in the direction normal to the second mating face, said mating faces being mounted to each other so that the first and second bone members form a compound bone device which prevents displacement of the first bone member with respect to the second bone member in both a longitudinal direction and a transverse direction when an anatomical load is applied;

each bone member defining a bore within its body which is angularly oriented with respect to a plane across its mating face and opens on said mating face, each bore being axially aligned with an angularly oriented bore defined in the body of the other bone member and a cortical pin member mounted in said axially aligned bores extending across said mating face in an interference fit to hold the first and second bone members in engagement resisting separation of the first and second bone members.

Claim 2. A compound bone device made from bone tissue as claimed in Claim 1 wherein each bone member has a body which defines at least two angularly positioned bores which are axially aligned with the angularly positioned bores of the other bone member, said bores being orientated at an oblique angle to a plane of each engaged mating surface and intersecting the plane of the mating surface and a pin member mounted in each of the aligned bores.

Claim 3. A compound bone device made from bone tissue as claimed in Claim 1 wherein one of the mating faces defines a plurality of bar members substantially parallel to the longitudinal axis of bone members and a plurality of bar members oriented transverse to the axis of the parallel bar members.

Claim 4. A compound bone device made from bone tissue for

implantation into a surgical site which supports an anatomical load applied to the compound bone device during a post-operative period while the implanted bone tissue is being resorbed and remodeled, comprising:

a first bone member defining a first mating face constructed and arranged to support a load in a direction that is normal to the first mating face and to receive and engage a complimentary mating face of a second bone member;

a second bone member defining a second mating face that is complimentary to the first mating face of the first bone member and is constructed and arranged to support a load in the direction normal to the second mating face, said mating faces being mounted to each other so that the first and second bone members form a compound bone device which prevents displacement of the first bone member with respect to the second bone member in both a longitudinal direction and a transverse direction when an anatomical load is applied, said first mating face defining at least one substantially planar surface and being provided with a plurality of intersecting channels to form a plurality of mating projections which define a first pattern thereon and said second mating face has at least one substantially planar surface and is constructed with a plurality of intersecting channels to form a second plurality of mating projections which define a second pattern thereon that is complimentary to the first pattern on the first planar face so that the first and second bone members can be engaged to prevent relative movement therebetween in the longitudinal and transverse directions when the compound bone device is supporting an anatomical load.

Claim 5. A compound bone device made from bone tissue as claimed in Claim 2 wherein said first angle is the inverse of the second angle.

Claim 6. A composite allograft bone device constructed of a plurality of bone members comprising a first bone member body defining with a face that includes a plurality of intersecting grooves cut into the face of the body to define a plurality of spaced projections; a second bone member body defining a face that includes a plurality of intersecting grooves cut into the face to form a plurality of spaced projections, said projections on said second face fitting into grooves cut in said first face and said projections on said first face fitting into grooves cut in said second face allowing the two bodies to be mated together, said mated bodies forming a composite bone device defining at least one throughgoing bore which is positioned at an angle to the longitudinal axis of

said composite device and a pin mounted in each said throughgoing bore extending into said bodies precluding the bodies from relative longitudinal movement.

Claim 7. The composite device of claim 6 wherein the majority of said projections have a rectangular profile with a planar top surface.

Claim 8. A sterile composite bone assembly made from allograft bone tissue comprising a plurality of at least three bone members, each bone member comprising a body defining an exterior surface and at least one mating face defining a plurality of spaced projections which interlock and fit within spaces formed between the projections of a mating face of another bone member and at least one pin member mounted in a bore formed in a body of each bone member extending at an angle across the interlocked mating faces with said at least one pin member extending past the mating faces but not extending past the exterior surface of the bone member body.

Claim 9. A sterile composite bone assembly made from a plurality of pieces of allograft bone tissue comprising a plurality of shaped bone members mounted together, each of which is provided with at least one mating face with a planar base surface, a plurality of spaced projections extending from said planar base surface, said projections being provided with a planar top which is parallel to said planar base surface and which engages the planar base surface of the opposing bone member and fits within spaces formed between the projections of a mating face of an opposing bone member.

Claim 10. A sterile composite bone assembly made from a plurality of pieces of preshaped bone tissue comprising a plurality of shaped bone members, each of which is provided with at least one mating face comprising a plurality of intersecting channels defining spaced projections which interlock and fit within spaces formed between the projections of a mating face of an adjacent shaped bone member to prevent horizontal movement in an axial direction and direction transverse to the axial direction with respect to each other.

Claim 11. A composite bone assembly comprising a plurality of bone members, each bone member defining at least one mating face with a plurality of spaced projections which interlock and fit within spaces formed between the projections of a mating face of another bone member, at least one of said bone members mating face projections comprising a plurality of projections with different sized rectangular geometric configurations, each bone member defining at least one bore which opens over a mating

face and is orientated at an acute angle thereto and at least one pin mounted in said at least one bore.

Claim 12. A sterile composite allograft bone device constructed of a plurality of sterile bone members comprising a first sterile bone member body with a mating face, said mating face defining a plurality of intersecting channels and a plurality of spaced projections; a second sterile bone member body with a mating face, said mating face defining a plurality of intersecting channels and a plurality of spaced projections, said projections on said second mating face fitting into channels of said first mating face and said projections on said first mating face fitting into channels of said second mating face allowing the bone member bodies to be mated together forming a sterile composite bone device, said sterile composite bone device defining at least one bore which is oriented at an angle to the longitudinal axis of said composite device and and intersects the mating faces of the mated bone member bodies and a pin mounted in each said bore extending into said bone member bodies precluding said bone member bodies from relative movement with respect to each other.

Claim 13. A composite bone assembly comprising a plurality of bone members, each bone member defining at least one mating face with a plurality of spaced projections extending from the mating face which interlock and fit within spaces formed between the projections of a mating face of another bone member, at least one of said bone members mating face projections comprising a plurality of projections with end surfaces in the same plane and configured in different sized rectangular geometric configurations, each bone member defining at least one bore which opens over a mating face and is positioned angularly thereto and at least one pin mounted in said at least one bore, the outer end surfaces of each pin being located within said composite bone assembly.

Claim 14. A sterile composite bone assembly made from a plurality of pieces of preshaped cortical bone tissue comprising a plurality of shaped bone members, each of which is provided with at least one mating face comprising a plurality of spaced projections forming a pattern which interlocks and fits within spaces formed between the projections of a mating face formed in a complimentary inverse pattern on another adjacent bone member, mechanical fastener means engaging at least two of said shaped bone members to hold them together.

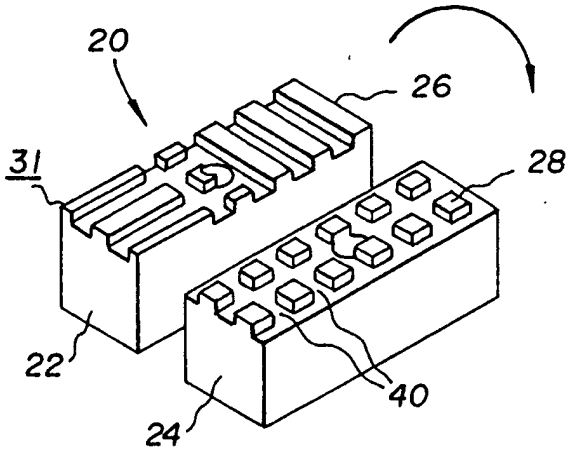

Fig. 1

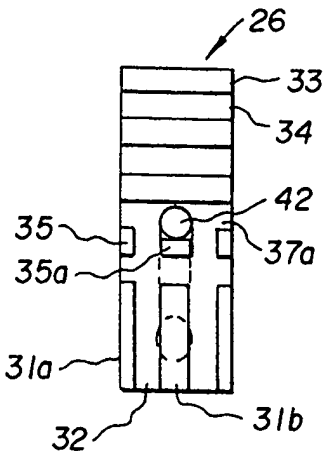

Fig. 2

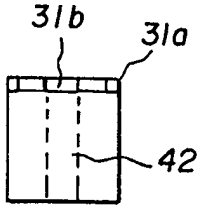

Fig. 3

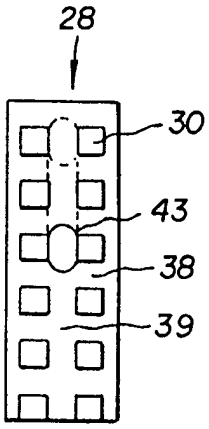

Fig. 4

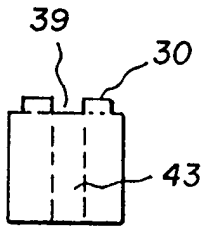

Fig. 5

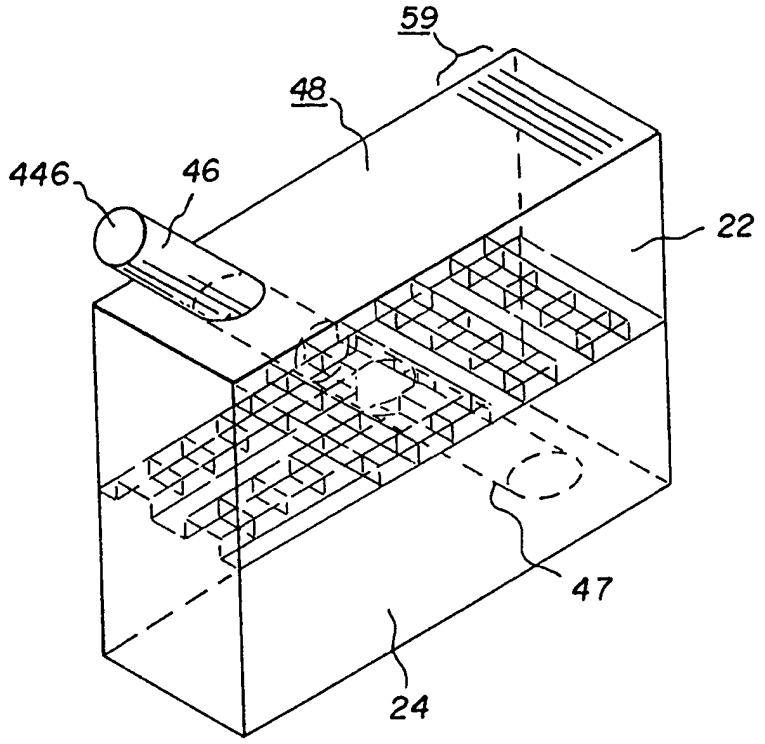
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Fig. 6

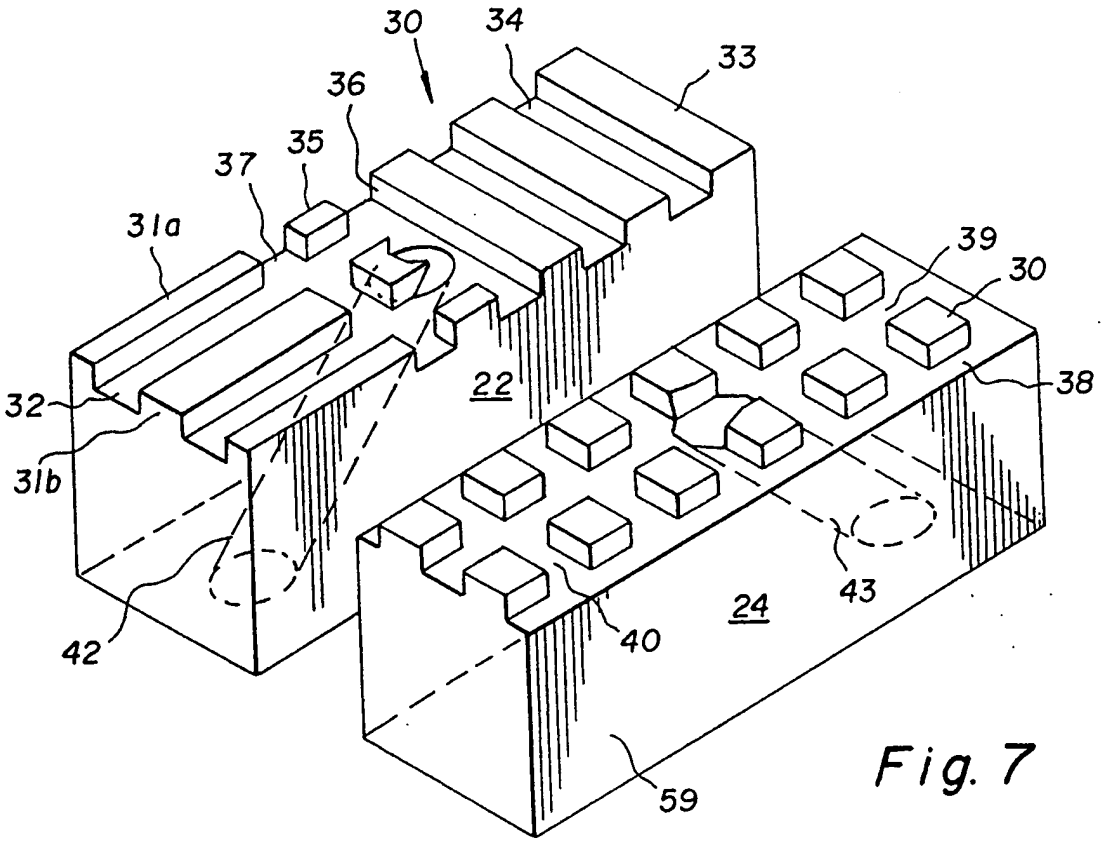
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Fig. 7

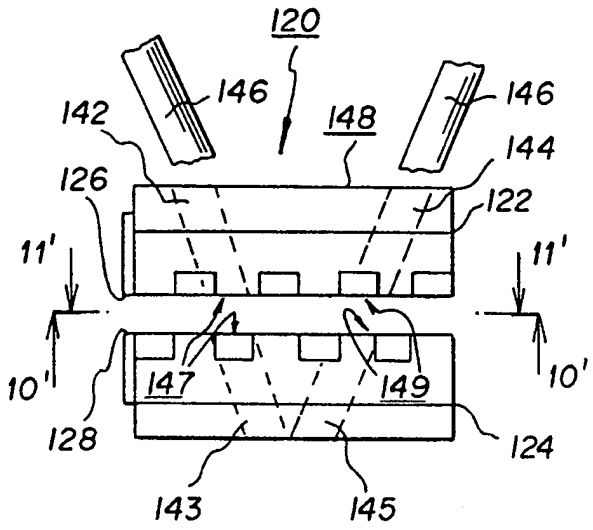


Fig. 8

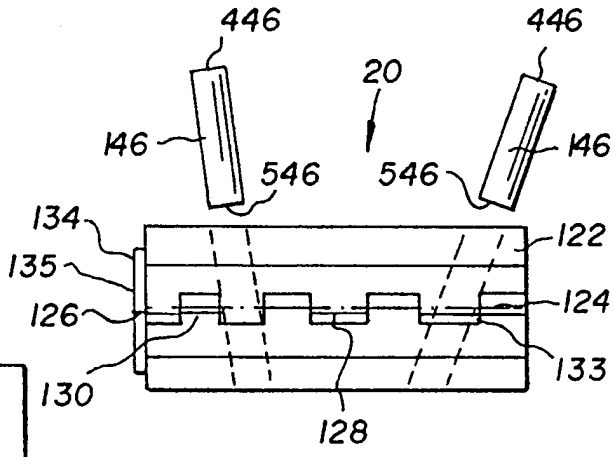


Fig. 9

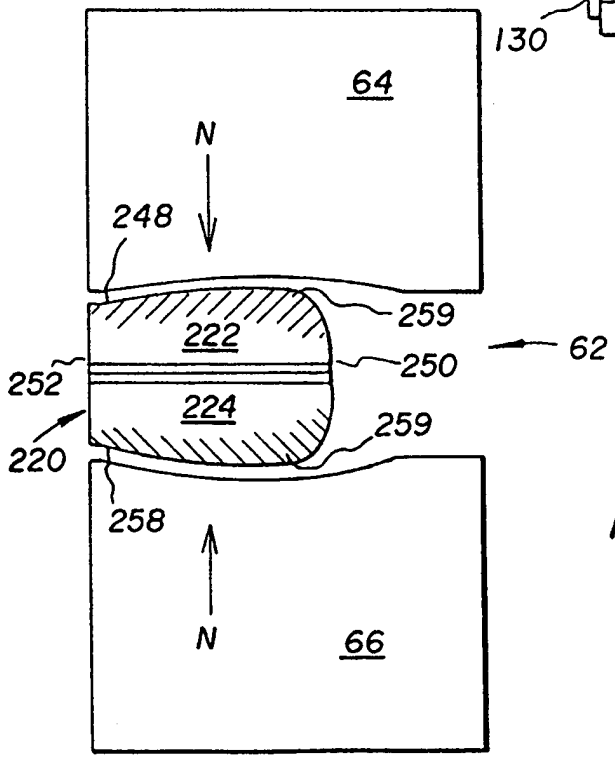


Fig. 14

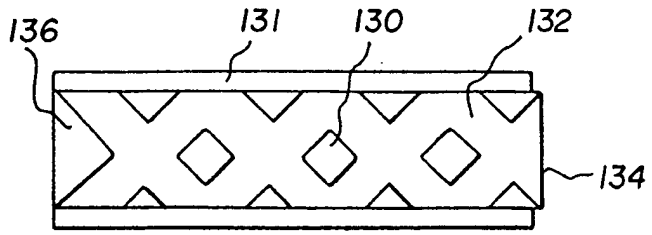


Fig. 10

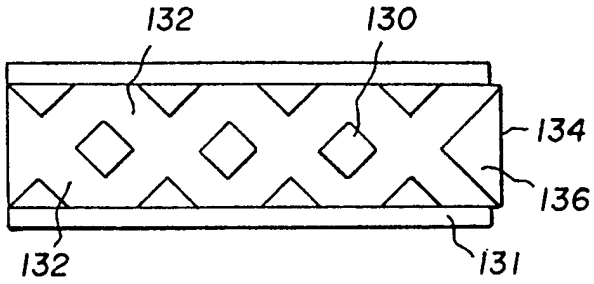


Fig. 11

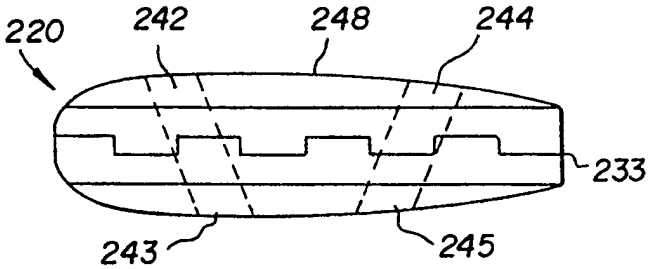


Fig. 12

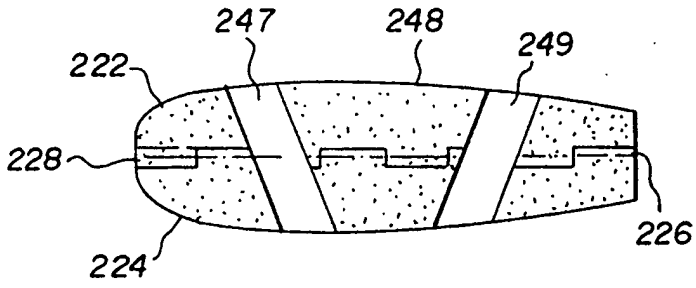
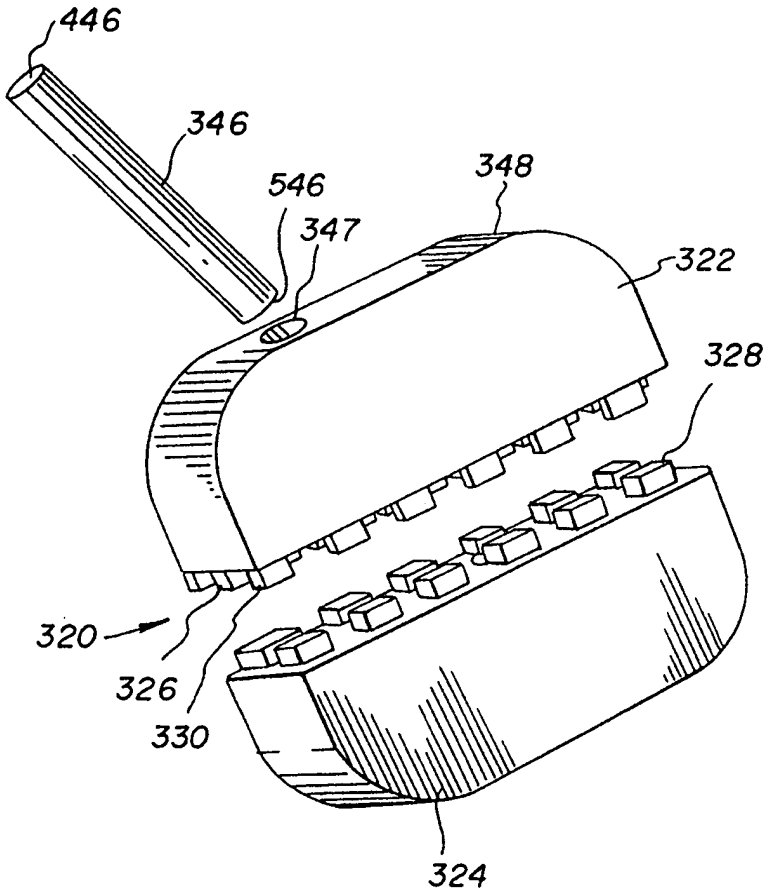


Fig. 13

Fig. 15



INTERNATIONAL SEARCH REPORT

International application No.
PCT/US99/26014

A. CLASSIFICATION OF SUBJECT MATTER

IPC(6) :A61F 2/28, 44
US CL : 623/16, 17

According to International Patent Classification (IPC) or to both national classification and IPC

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)

U.S. : 623/16, 17

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

Electronic data base consulted during the international search (name of data base and, where practicable, search terms used)

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
A	US 5,405,391 A [HENDERSON et al.] 11 April 1995, col. 5 lines 1-17,and Fig. 5.	1-14
A	US 5,571,190 A [ULRICH et al.] 05 November 1996, col. 4 lines 41-45, 52-67; col. 5 lines 25, 26, 44-49; and Fig. 1.	1-14
A,P	US 5,865,848 A [BAKER] 02 February 1999, col. 5 lines 1-24.	1-14
A,P	US 5,888,222 A [COATES et al.] 30 March 1999, col. 1 lines 66, 67; and Fig. 1.	1-14
A,P	US 5,899,939 A [BOYCE et al.] 04 May 1999, col. 3 lines 12-16, and col. 6 lines 27-37.	1-14

☐ Further documents are listed in the continuation of Box C. ☐ See patent family annex.

*	Special categories of cited documents:	"T"	later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention
"A"	document defining the general state of the art which is not considered to be of particular relevance	"X"	document of particular relevance; the claimed invention cannot be considered novel or cannot be considered to involve an inventive step when the document is taken alone
"E"	earlier document published on or after the international filing date	"Y"	document of particular relevance; the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art
"L"	document which may throw doubts on priority claim(s) or which is cited to establish the publication date of another citation or other special reason (as specified)	"&"	document member of the same patent family
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"P"	document published prior to the international filing date but later than the priority date claimed		

Date of the actual completion of the international search 27 JANUARY 2000	Date of mailing of the international search report 29 FEB 2000
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